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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.                 | CONFIRMATION NO.       |
|---|-------------|----------------------|-------------------------------------|------------------------|
| 10/825,580  | 04/15/2004  | Anja Kohlrausch      | I/1491US                            | 8666                   |
| 28501   | 7590        | 06/26/2007           |                                     |                        |
| MICHAEL P. MORRIS<br>BOEHRINGER INGELHEIM CORPORATION<br>900 RIDGEBURY ROAD<br>P. O. BOX 368<br>RIDGEFIELD, CT 06877-0368 |             |                      | EXAMINER<br>KASIREDDY, CHANDRAPRAKA |                        |
|   |             |                      | ART UNIT<br>1609                    | PAPER NUMBER           |
|   |             |                      | MAIL DATE<br>06/26/2007             | DELIVERY MODE<br>PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/825,580

**Applicant(s)**

KOHLRAUSCH, ANJA

**Examiner**CHANDRAPRAKASH  
KASIREDDY**Art Unit**

1609

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>04/15/2004&amp;11/26/2004</u> .                               | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:  
A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1- 19 are rejected under 35 U.S.C. 102(a) as being anticipated by Riedel et al. (US 2004/0259925 A1, filing date Jan 14, 2004, provisional filled on Feb 11, 2003).

The instant claims are related to pharmaceutical composition comprising telmisartan sodium salt and a diuretic, which further comprising one or more excipients.

Riedel et al. teaches a pharmaceutical composition comprising telmisartan, atorvastatin and a diuretic, optionally with one or more excipients for the prevention or treatment of cardiovascular, cardiopulmonary or renal diseases. Wherein the formulation of the pharmaceutical composition comprises 20- 200 mg. telmisartan, atorvastatin (2.5 –40 mg) and wherein the diuretic consists of 10-50 mg of hydrochlorothiazide. (See claims 14,17& 18)

Riedel et al. teaches preparation of crystalline telmisartan sodium salt starting from telmisartan (see page 11, paragraph 0148-0150) and also teaches the formulation of hydrochlorothiazide, telmisartan sodium salt, sorbital and red iron oxide were mixed in a free blender passed through a 0.8 mm screen and the addition of magnesium stearate, processed in a free fall blender to obtain a

powdered mixture. This combination of active substances and excipients was then compressed with a suitable tablet press to form tablets. The quantity of telmisartan sodium salt contained in each tablet corresponding to a quantity of 80 mg of the free acid of telmisartan. (See page 11, paragraph 0145-0146).

Riedel et al. further discloses the combination of active substances are generally incorporated with one or more formulation adjuvants such as mannitol, sorbitol, xylitol, sacchrose, crosmellose sodium, polyvinylpyrrolidone, water/glycerol, water/sorbitol etc. (See page 7, paragraph 0083).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakatani et al., (US 2004/010813 A1, Filing date Sep 18, 2003) in view of Donsbach et al. (US 2003/0130331 A1, filing date Oct. 30, 2002) and Lacourciere et al. (American J Therapeutics. 2002, 9(2) page 111-7).

The instant claims are related to pharmaceutical composition comprising telmisartan sodium salt and a diuretic, and further comprising one or more excipients. The pharmaceutical composition, wherein the diuretic is hydrochlorothiazide, amount of hydrochlorothiazide is 10 to 15 mg or 20-30 mg, wherein the amount of telmisartan salt is 60-to 90 mg and further specific to 40 to 45 mg. Further, the pharmaceutical composition comprises compressed dry granules comprising a telmisartan sodium salt and mannitol, magnesium stearate and hydroxypropyl cellulose and a mixture of hydrochlorothiazide, with excipients

Nakatani et al. teaches solid pharmaceutical compositions comprising angiotensin II receptor antagonist telmisartan in the form of granules or in the form of a powder, as well as solid oral formulations ready for use/ingestion, capsule and tablet formulations made from said pharmaceutical compositions and also provides methods for producing such compositions and formulation. (See page 1, paragraph 002 and page 3, paragraph 0057).

Nakatani et al. further teaches the total composition of capsule and tablets formulations may vary with the following ranges, 10 mg to 160 mg of telmisartan, preferably 20 mg to 80 mg of telmisartan, most preferred 35 mg to 45 mg of telmisartan, and non ionic surfactants, soluble diluents selected from mannitol,

erythritol, sorbitol, and excipients/ adjuvants such as cellulose powder, microcrystalline cellulose, cellulose derivatives hydroxymethyl cellulose, hydroxypropyl cellulose, hydroxyethyl cellulose, and hydroxypropyl methyl cellulose, corn starch, pregelatinized starch, sodium stearyl fumarate, magnesium stearate, detergents sodium starch glucolates, croscarmellose, povidone (page 2, para 0025 to 0027 and page 3, paragraph 0060 to 77). The tablet formulations according to the invention can also be used for the preparation of fixed dose combination products, for instance with diuretics as the second active component. Suitable diuretic agents are Hydrochlorothiazide, clopamide, xipamide or chlorotalidone. (Column 4, paragraph 0078).

Lacourciere et al. teaches a fixed-dose combination of 40 mg of the angiotension II antagonist telmisartan plus 12.5 mg of diuretic hydrochlorothiazide (HCTZ) was superior to 40 mg telmisartan in patients with mild to moderate hypertension that failed to respond adequately to 40 mg telmisartan monotherapy.

It would have been obvious to one ordinary skill of the art at the time the invention was made to employ telmisartan and hydrochlorothiazide in the composition by Nakatani et al. and Lacourciere et al. release fixed dose combination of 40 mg telmisartan plus 12.5 mg hydrochlorothiazide is clinically superior in patients with mild to moderate hypertension. It would have also been obvious to combine pharmaceutical composition and dosage strengths.

Donsbach et al. teaches a crystalline sodium salt of telmisartan, process for preparation and use thereof for preparing a pharmaceutical composition (abstract and page 6 table 1 and 2 for formulation). The advantage of the sodium salt form of telmisartan is to provide a new stable, crystalline form of telmisartan, which provides stability of the starting material under different environmental conditions, the stability during manufacturing of the pharmaceutical formulation and stability in the final compositions of the pharmaceutical preparation. (See column 2 lines 25-27 and column 1 lines 64-67).

In view of the explicit teachings of Nakatani et al and Donsbach et al., it would have been obvious to a person of ordinary skill in the art to further modify the pharmaceutical composition in view of solubility and stability with sodium salt of telmisartan and diuretic hydrochlorothiazide combination. Thus the claimed invention is obvious over Nakatani et al. in view of Lacourciere et al. and Donsbach et al. Optimization of amounts to be included in pharmaceutical composition are also within the purview of the skilled artisan and is therefore obvious.

### ***Conclusion***

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see

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<http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHANDRAPRAKASH KASIREDDY whose telephone number is (571) 272-1600. The examiner can normally be reached on 9.00 AM TO 5.00 PM (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JEFFREY STUCKER can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

CCPR.



JEFFREY STUCKER  
SUPERVISORY PATENT EXAMINER